

Panosec Tablet 40mg

Pantoprazole Sodium Sesquihydrate

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1. What Panosec Tablet 40mg is used for

Panosec Tablet 40mg is used for treatment of :

- An infection with a bacterium called *Helicobacter pylori* in people with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning.
- For duodenal ulcer
- For gastric (stomach) ulcer
- Moderate or severe reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitating of stomach acid)
- Zollinger-Ellison syndrome and other conditions producing too much acid in the stomach as long term treatment.

2. How Panosec Tablet 40mg works

Panosec Tablet 40mg is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach

3. Before you use Panosec Tablet 40mg

When you must not take it

Do not take Panosec Tablet 40mg:

- if you are allergic (hypersensitive) to pantoprazole or any of the other ingredients of Panosec Tablet 40mg.
- if you are allergic to medicines containing other proton pump

inhibitors.

Before you start to take it

Take special care with Panosec Tablet 40mg

- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. Doctor will check your liver enzymes more frequently, especially when you are taking Panosec Tablet 40mg as a long- term treatment. If the liver enzyme levels increase, then treatment should be stopped.
- If you need to take medicines called NSAIDs continuously with prescribed Panosec Tablet 40mg because you have an increased risk of developing stomach and intestinal complications.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole as a long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking a medicine containing atazanavir (for the treatment of human immunodeficiency virus (HIV)-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A)

Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women.

If you are pregnant, or think you may be pregnant, or if you are breast-feeding, you should use this medicine only if your doctor considers the benefit for you to be greater than the potential risk for your unborn child.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You should not drive or operate machinery until you know how the medicine affects you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because Panosec Tablet 40mg can affect the way some other medicines work. Also, other medicines can affect the way Panosec Tablet 40mg works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Panosec Tablet 40mg:

- atazanavir (antiretroviral medicine for treating HIV)
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood.
- ketoconazole (an antifungal – to treat fungal infection).

4. How to take Panosec Tablet 40mg

How much to take

Adults and adolescents 12 years of age and above:

Treatment of reflux oesophagitis

The usual dose is one pantoprazole 40mg tablet a day. Sometimes, your doctor may tell you to increase to 2 tablets daily.

Adults:

Treatment of infection with *Helicobacter pylori* in combination with two antibiotics

One pantoprazole 40mg tablet, two times a day plus two antibiotics either amoxicillin, clarithromycin or metronidazole, each to be taken two times a day with your pantoprazole tablet.

The following combinations are recommended:

- a) 2 x 1 Panosec 40 mg gastro-resistant tablet / day
+ 2 x 1000 mg amoxicillin / day
+ 2 x 500 mg clarithromycin / day
- b) 2 x 1 Panosec 40 mg gastro-resistant tablet / day
+ 2 x 500 mg metronidazole / day
+ 2 x 500 mg clarithromycin / day
- c) 2 x 1 Panosec 40 mg gastro-

resistant tablet / day
+ 2 x 1000 mg amoxicillin / day
+ 2 x 500 mg metronidazole / day

Treatment of stomach and duodenal ulcers

The usual dose is one pantoprazole 40mg tablet a day. In certain cases, the dose may be doubled.

Long-term treatment of Zollinger Ellison syndrome and other conditions in which too much stomach acid is produced

The recommended starting dose is usually two pantoprazole 40mg tablets a day. Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, take the tablets twice daily.

Children

These tablets are not recommended for use in children.

When to take it

Take the tablets 1 hour before a meal, without chewing or crushing them, and swallow them whole with some water.

For *Helicobacter pylori* eradication therapy, the second pantoprazole 40mg tablet should be taken before your evening meal.

How long to take it

Always take Panosec Tablet 40mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Treatment of reflux oesophagitis The treatment period is usually between 4 and 8 weeks.

Treatment of infection with Helicobacter pylori in combination with two antibiotics

The usual treatment period is 1- 2 weeks.

Treatment of stomach and duodenal ulcers

The treatment period for stomach ulcers is usually between 4-8 weeks. The treatment period for duodenal ulcers is usually 2- 4 weeks.

Long-term treatment of Zollinger

Ellison syndrome and other conditions in which too much stomach acid is produced

The treatment period is usually between 4 and 8 weeks.

If you forget to take it

Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

If you take too much (overdose)

Tell your doctor or pharmacist. There are no known symptoms of overdose.

5. While you are using Panosec Tablet 40mg

Things you must do

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do

Do not stop taking these tablets without first talking to your doctor or pharmacist.

Things to be careful of

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered. If you take Panosec Tablet 40mg on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

6. Side Effects

The most commonly reported ADRs are diarrhoea and headache.

When you are taking this medicine,

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your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints. (Subacute Cutaneous Lupus Erythematosus, SCLE)
 - Fever, extreme tiredness, pus/blood in urine.
 - Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
 - Fracture in the hip, wrist or spine
 - Watery stool, stomach pain and fever that do not go away.
 - Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).
- a) Subacute Cutaneous Lupus Erythematosus (SCLE)
Frequency “not known”
 - b) Interstitial Nephritis
Kidney problems (interstitial nephritis)
 - c) Hypomagnesaemia
Frequency “not known”: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
 - d) Fracture
Frequency uncommon”: Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)
 - e) Clostridium Difficile Diarrhea
Severe diarrhea which may be caused by an infection (Clostridium difficile) in your intestines.
 - f) Fundic Gland Polyps (Benign)
Frequency “Common”: Benign polyps in the stomach.
 - g) Vitamin B12 Deficiency
Proton pump inhibitors may cause vitamin B12 deficiency.

Frequency 'not known':
Inflammation in the large bowel,
that causes persistent watery
diarrhea

You may report any side effects or
adverse drug reactions directly to the
National Centre for Adverse Drug
Reaction Monitoring by visiting the
website npa.gov.my [Consumers →
Reporting Side Effects to Medicines
(ConSERF) or Vaccines (AEFI)]

7. Storage Condition

Store below 30°C and protect from
moisture.

8. Product Description

What it looks like

Panosec Tablet 40mg: Yellow to pale
yellow, oval, biconvex delayed
release tablets imprinted 'H126' on
one side with black ink and plain on
the other side.

Ingredients

Active ingredient

Pantoprazole Sodium Sesquihydrate

Inactive ingredients

Lactose Monohydrate

Hydroxy propyl cellulose

Calcium stearate

Sodium Carbonate

Anhydrous Sodium lauryl sulphate

Hypromellose

Ferric oxide, Yellow

Propylene glycol

Titanium dioxide

Methacrylic acid - Ethylacrylate
copolymer (1:1) dispersion 30%

Triethyl citrate

Polysorbate 80

MAL18086142AZ

9. Manufacturer

Hetero Labs Limited

Unit V, Sy.No 439, 440, 441 &

458, TSIIC Formulation SEZ,

Polepally Village, Jadcherla

Mandal, Mahaboobnager, Dist

Telangana, 509301 India

Product Registration Holder

Duopharma Marketing Sdn.Bhd.,

Lot 2, 4, 6, 8 & 10, Jalan P/7,

Section 13, Bangi Industrial Estate,

43650 Bandar Baru Bangi, Selangor

Darul Ehsan, Malaysia.

10. Date of revision

03/01/2022

11. Serial Number

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